REMARKS

Applicants have studied the Office Action of June 14, 2001 ("Office Action"), and have made amendments to the claims. It is respectfully submitted that the application, as amended, is in condition for allowance. Claims 10, 12-18, 20-23, and 43-71 are pending in the present application. The applicants have canceled claims 10, 59, and 71, amended claim 62, and added claims 72-79. No new matter has been added. Reconsideration and allowance of the claims in view of the foregoing amendments and the ensuing remarks are respectfully requested.

The Applicants thank the Examiner for allowing claims 43-58 and 60-62.

The Examiner objected to claim 10, stating that it depends on canceled 2 and therefore requires correction. The Applicant has canceled claim 10 and rewritten it as new claim 72; claim 72 depends on claim 47, which the Examiner has allowed. The Applicant respectfully submits that because claim 47 is allowable, claim 72 should be allowable, as well.

The Examiner objected to claims 59 and 71 under 37 C.F.R. § 1.75(c), stating that the claims are in improper dependent form for failing to further limit the subject matter of the previous claim. The Examiner suggested that the Applicants rewrite these claims in independent form. The Applicants have done as the Examiner has suggested; the Applicants have rewritten claim 59 as independent claims 73-76, and have rewritten claim 71 as claims 77-79. The Applicants respectfully submit that these claims fully comport with the requirement of § 1.75(c), and respectfully request that the Examiner withdraw the objection under that section.

The Examiner objected to claim 62, stating that there is a dash at the end of it. The Applicants have amended claim 62 by removing the dash. The Applicants respectfully request that the Examiner withdraw the objection to this claim.

The Examiner rejected claims 63-71 under 35 U.S.C. § 112, second paragraph, stating that the claims are "vague and indefinite in the recitation of the term 'substantially,' which is a conditional term and renders the claim indefinite." The Applicants respectfully traverse this rejection.

One of ordinary skill in the art would have no difficulty discerning the meaning of "substantially" and determining the scope of the claims. "Substantially similar" has

definite meaning. The specification explicitly provides it: "As used herein, the phrase 'substantially the same nucleotide sequence' refers to DNA having sufficient homology to the reference nucleotide, such that it will hybridize to the reference nucleotide under typical moderate stringency condition." Page 9, lines 5-8. Moreover, such DNA must have "at least 60% homology with respect to the referenced nucleotide sequence." Page 9, lines 9-10. The claim itself reinforces this meaning set forth in the specification. It requires that the nucleotide be sufficiently similar so that it "binds transferrin when the nucleotide is transfected into a cell that lacks transferrin receptors and the cell is incubated with 5 μg/ml of transferrin in nutrient media for 30 min on ice." These are concrete, specific definitions; anyone of ordinary skill in the art (and the level of skill in this art is quite high) would be able to recognize the meaning of "substantially similar" in light of the specification. See In re Marosi, Stabenow, and Schwarzmann, 218 U.S.P.Q. 289, 292 ("It is well established that 'claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification'").

The Examiner states that the Applicants could obviate the rejection under § 112, first paragraph, by "supplying specific conditions supported by the specification which Applicant considers to be 'substantial.'" The Applicant has already done so, as explained above. In any event, there is no requirement that an applicant use "specific conditions" to claim an invention. The Applicant is required to use no more than a "reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire." MPEP § 2173.02. The courts have consistently upheld this principal. The Federal Circuit has observed, for example, that terms such as "close to," "substantially equal," and "closely approximate," are "ubiquitous in patent claims," and strongly disapproved of the contention that such terms are "not specifically or precisely defined . . . to accept [this] contention would turn the construction of a patent into a mere semantic quibble that serves no useful purpose." Andrew Corp. v. Gabriel Electronics Inc., 6 U.S.P.Q.2d 2010, 2012-2013 (Fed. Cir. 1988); see also Atmel Corp. v. Information Storage Devices, Inc., 997 F.Supp. 1210, 1228-1229 (N.D. Cal. 1998) ("substantially all" held definite despite "slight uncertainty about [its] precise meaning").

The Applicants respectfully submit that the terms "substantially similar" are definite terms, that the specification provides explicit guidance as to what the terms mean, and that those of ordinary skill in the art would fully and readily understand them. On these grounds, the Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 112, second paragraph.

The Examiner further rejected claims 63-71 under 35 U.S.C § 112, first paragraph, stating that the specification "does not reasonably provide enablement for nucleotide sequences which are 'substantially the same as' nucleic acid sequences consisting of SEQ ID NO: 2 and 3." This rejection is respectfully traversed.

The Examiner argues that there are a "myriad of nucleic acid sequences . . . encompassed by the claim," and that the specification does not disclose how one can be sure that any of these sequences will "retain the function of binding transferrin." In describing the claims this way, the Examiner leaves out an important limitation: a nucleotide sequence does not fall within the scope of the claims unless it "encodes a polypeptide that binds transferrin when the nucleotide is transfected into a cell that lacks transferrin receptors and the cell is incubated with 5 µg/ml of transferrin in nutrient media for 30 min on ice." The range of nucleotide sequences that the claims encompass is therefore not as broad as the Examiner states; not only must a nucleotide sequence be "substantially similar" to the nucleotide sequences recited in the specification, but it must also pass a specific functional test.

The Applicant respectfully submits that the standard for enablement is not as severe as the Examiner has put it. As long as an applicant "discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied." MPEP 2164.01(b) (emphasis added). Claims may be enabled even if those skilled in the art reasonably disagree as to whether they are enabled or not. Bio-Technology General Corp. V. Genentech, Inc., case no. 00-1223, -1267 (Fed. Cir., September 27, 2001). But here, the Applicant has done precisely as the MPEP has required: the applicant has disclosed, over 12 full pages of the specification, examples that describe at least a dozen cell lines that may be used to derive the nucleic acid sequences of the invention, a procedure to clone cDNA and genomic DNA isolated from these cell lines, a chromosomal mapping technique to identify genes carrying the

nucleic acid sequences of the invention, and Northern blot, reverse-transcriptase chain reaction, transfection, flow cytometric analysis, and other techniques to evaluate and isolate the these sequences. See pages 21-33 of the application. This procedure enables any one of ordinary skill in the art (and the Applicants repeat here their observation that the level of skill in the art is very high) to make and use the nucleic acids of the invention commensurate in scope with the claims.

This is not to say that one seeking to identify nucleic acids other than those disclosed in the specification will not have to conduct experiments to do so. But experimentation is permissible. Even "a considerable amount of experimentation is permissible, if it is merely routine." In re Wands, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). In United States v. Telectronics, Inc., 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988), for example, competitors had to experiment for 6 to 12 months, call upon four different specialtists (an electrical engineer, a surgeon, a biomechanic, and a biologist), and spend $50,000 to determine how to practice the invention at issue; yet even this amount of experimentation was not undue, because the steps required to carry it out were routine. The same principal applies in the present application. Those of ordinary skill in the art will have to execute no more than routine steps – all of which the specification describes in many pages of detail – to identify and use nucleic acid sequences which are "substantially similar" to the sequences identified in the specification. The Applicants therefore respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 112, first paragraph.

For the foregoing reasons, the Applicants believe that the application is condition for allowance, and respectfully request early, favorable action on the merits. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call either of the undersigned attorneys at the Los Angeles telephone number (213) 488-7100 to discuss the steps necessary for

placing the application in condition for allowance should the Examiner believe that such a telephone conference would advance prosecution of the application.

Respectfully submitted,

PILLSBURY WINTHROP LLP

Date: ~~September~~ October 5, 2001

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APPENDIX

IN THE CLAIMS:

The Applicants have canceled claims 10, 59, and 71 and amended claim 62 as follows:

62. (Amended) The isolated host cell of claim 61, wherein the promoter is selected from the group consisting of T7, metallothionein I, and polyhedrin promoters.[—]

The Applicants have added claims 72-79.